IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,) REDACTED – PUBLIC VERSION
Plaintiffs,	Civil Action No. 07-333-SLR Civil Action No. 07-348-SLR
v.	Civil Action No. 07-409-SLR
JOHNSON & JOHNSON, INC. and CORDIS CORPORATION,)))
Defendants.)))

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE ASSERTED CLAIMS OF THE '7286, '3286, AND '473 PATENTS-IN-SUIT

Of Counsel:

Richard L. DeLucia Paul M. Richter, Jr. Michael K. Levy KENYON & KENYON LLP One Broadway New York, NY 10004 (212) 425-7200 YOUNG CONAWAY STARGATT & TAYLOR LLP

Josy W. Ingersoll (#1088) [jingersoll@ycst.com] Karen L. Pascale (#2903) [kpascale@ycst.com] Karen E. Keller (#4489) [kkeller@ycst.com] Andrew A. Lundgren (#4429) [alundgren@ycst.com] The Brandywine Building, 17th Floor 1000 West Street Wilmington, DE 19801 (302) 571-6600

Attorneys for Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc.

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Plaintiffs Boston Scientific Corp. and Boston Scientific Scimed, Inc. (collectively, "BSC") respectfully submit this reply brief in further support of their motion for summary judgment that the accused PROMUS™ Everolimus-Eluting Coronary Stent ("the PROMUS stent") does not infringe (either literally or under the doctrine of equivalents) any of the claims of U.S. Patent No. 7,217,286 ("the '7286 patent")¹, U.S. Patent No. 7,223,286 ("the '3286 patent"), and U.S. Patent No. 7,229,473 ("the '473 patent") asserted by defendants Cordis Corp. and Johnson & Johnson, Inc. (collectively, "Cordis") when certain of BSC's proposed claim constructions are applied. This motion, along with Plaintiffs' Opening Brief in Support of Their Motion for Summary Judgment of Non-Infringement of the Asserted Claims of the '7286, '3286, and '473 Patents-in-Suit ("BSC's Opening Br."), was filed on September 16, 2009. (See D.I. 260.)² Cordis filed its opposition, entitled Defendants/Counter-Plaintiffs Johnson & Johnson and Cordis Corporation's Opposition to Plaintiffs' Motion for Summary Judgment of Non-Infringement of the Asserted Claims of the '7286, '3286, and '473 Patents-in-Suit ("Cordis Resp. Br."), on October 9, 2009. (See D.I. 305.)

INTRODUCTION

Cordis's opposition to BSC's motion for summary judgment of non-infringement is flawed for a number of reasons:

First, Cordis's opposition fails to understand, misapplies, or conflates BSC's proposed claim constructions with its own. While Cordis and its experts purport to explain how the PROMUS stent meets various limitations of the '7286, '3286, and '473 patents under BSC's

Exhibits 1 through 116 refer to exhibits attached to the *Appendix in Support of BSC's Motions for Summary Judgment of Non-Infringement and Invalidity Pursuant to 35 U.S.C. § 103*, which was filed concurrently with BSC's Opening Brief as D.I. 263.

Unless otherwise noted, any docket index numbers present in this brief refer to papers filed in connection with C.A. No. 07-333.

constructions, the allegedly disputed "facts" Cordis and its experts point to make clear that they are simply applying Cordis's own faulty constructions. In other words, Cordis's opposition amounts to nothing more than a re-casting of its claim construction arguments.

Second, Cordis relies on untimely and inadmissible expert opinions (including brand new opinions that were never before disclosed and were apparently manufactured for the specific purpose of opposing BSC's motion). Such inadmissible evidence cannot properly support a denial of summary judgment.

Third, Cordis cites to numerous irrelevant and non-material facts in an apparent effort to draw attention away from its own admissions, which compel the entry of summary judgment of non-infringement. Cordis's attempts to manufacture supposedly genuine issues of material fact in a case where no such issues exist should not be countenanced.

Fourth, Cordis fails to recognize that the doctrine of equivalents does not apply in this case. The application of the doctrine to the limitations addressed by BSC's motion would wholly eliminate those limitations from the claims and render them meaningless.

When BSC's proposed constructions are properly applied, there can be no dispute that the PROMUS stent does not infringe any of the asserted claims of the '7286, '3286, and '473 patents. The Court need not find in BSC's favor with regard to all of the limitations addressed in its opening brief in order to grant BSC's motion for summary judgment; a finding in BSC's favor in connection with *any* of those limitations would support entry of summary judgment in connection with numerous asserted claims. Cordis's opposition brief and accompanying expert declarations admit all of the material facts – albeit buried in a mountain of extraneous and immaterial observations – needed to establish non-infringement as a matter of law.

ARGUMENT

I. "Biocompatible" Claim Limitations

All of the asserted claims of the '7286, '3286, and '473 patents require the use of "biocompatible" polymeric materials. Cordis argues at length that material issues of fact exist regarding whether the polymeric materials utilized by PROMUS are in fact "biocompatible." The evidence that Cordis cites, however, simply does not preclude summary judgment. While Cordis may wish otherwise, "[f]actual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

As BSC explained in its claim construction briefing, the term "biocompatible" can only be properly construed to mean "does not elicit any negative tissue reaction or promote mural thrombosis." (See Plaintiffs' Opening Markman Brief (D.I. 254) at 12-14; Plaintiffs' Responsive Markman Brief (D.I. 309) at 10-15.) This is because the specification of the patents-in-suit expressly defines the term in this manner. (See Ex. 1, '7286 Patent, 6:37-39 (BSC-SJA-0017).) Under this construction, a polymeric coating that elicits any negative tissue reaction whatsoever – no matter how small – falls outside the scope of the claims.

There are no material facts that prevent entry of summary judgment of non-infringement if the Court adopts this proper construction of "biocompatible." Cordis's opposition briefing and expert declarations show that Cordis *does not dispute* that PROMUS causes at least some inflammation when implanted in the body. Cordis also does not appear to dispute that inflammation in the coronary vasculature constitutes a "negative tissue reaction." These concessions — which are the only facts that have any relevance to whether the PROMUS stent

meets the "biocompatible" claim limitations under BSC's proposed construction – show that there are no genuine issues of material fact precluding entry of summary judgment here.³

Cordis's argument that PROMUS can meet the claims' "biocompatible" limitation as long as the amount of inflammation caused upon implantation is "clinically acceptable" or "within recognized safety limits" ignores the explicit definition of "biocompatible" set forth in the 1997 patents' specification.⁴ In effect, Cordis's summary judgment opposition is nothing more than a rehashing of its own claim construction positions and another attempt to apply its own construction of "biocompatible," which extends to any polymeric material able to perform its function in the body with an "acceptable biological response." ⁵

Cordis's suggestion that BSC has not informed regulatory authorities or medical professionals that PROMUS causes a "negative tissue reaction" (see Cordis Resp. Br. at 7) is simply incorrect.

Cordis's complaint that BSC's summary judgment motion should be denied because, if granted, it may be difficult for Cordis to prove that any device infringes the claims of the '7286, '3286, and '473 patents (see Cordis Resp. Br. at 5) is unpersuasive. See Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("Even a nonsensical result does not require the court to redraft ... claims...."); K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, [they] give effect to the terms chosen by the patentee").

In any event, it is unclear why Cordis thinks that BSC would have an obligation to inform regulatory authorities or medical professionals that PROMUS does not meet the special definition of "biocompatible" provided by an obscure Cordis patent. This in no way constitutes evidence of infringement.

Cordis's resort to the doctrine of equivalents in an attempt to raise a genuine issue of fact is also unavailing. It is well settled that, "if a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 n.8 (1997); see Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed. Cir. 1998). Allowing the claim term "biocompatible," which, properly construed, limits the claims to stents which elicit no inflammation, to extend to materials that elicit some inflammation, would impermissibly read that limitation out of the claims. See, e,g, Warner-Jenkinson, Co., 520 U.S. at 29-30; Carnegie Mellon Univ. v. Hoffmann-La Roche Inc., 541 F.3d 1115, 1129 (Fed. Cir. 2008); Asyst Techs., Inc. v. Emtrak, Inc., 402 F.3d 1188, 1195 (Fed. Cir. 2005); Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1358 (Fed. Cir. 2005). The Federal Circuit has repeatedly refused to apply the doctrine of equivalents in such circumstances. See, e.g., Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc., 291 F.3d 1317, 1321-22 (Fed. Cir. 2002) (a connection "above" two plugs cannot be equivalent to a connection "between the two plugs" because such application of the doctrine of equivalents "would vitiate [the] limitation[, requiring the connection to be positioned between the two plugs,] and thereby run

afoul of the all-limitations rule"); *Moore U.S.A., Inc. v. Standard. Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) (a "majority" cannot be equivalent to a "minority" because such application of the doctrine of equivalents would render the claim limitation, requiring that "strips of adhesive ... extend the majority of the lengths" meaningless) (alteration in original); *Novartis Pharm. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1312 (Fed. Cir. 2004) ("the formation of a particulate dispersion inside the body cannot infringe under the doctrine of equivalents because this would vitiate the claimed requirement that the dispersion be prepared outside the body").

This is not a case, as Cordis would have the Court believe, where the claims allow for "X amount of inflammation," but PROMUS causes only a slightly different "X+1 amount of inflammation." Instead, PROMUS does the *exact opposite* of what the claims require. Even Cordis acknowledges that the doctrine of equivalents cannot be applied in cases "where the accused device contain[s] *the antithesis* of the claimed structure." (Cordis Resp. Br. at 9 (quoting *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1330 (Fed. Cir. 2009).)

Finally, as BSC noted in its opening brief, application of the doctrine of equivalents to the "biocompatible" limitation is even more inappropriate in light of Cordis's specification and prosecution disclaimers. (See BSC's Opening Br. at 18-19.) While Cordis attempts to argue that these disclaimers are meaningless, Cordis cannot have it both ways. Cordis has repeatedly argued that the subject matter claimed by the patents-in-suit is different from and unexpected in view of the prior art because it employs "biocompatible" polymeric materials. If Cordis insists on making such arguments, it is simply not entitled to resort to the doctrine of equivalents when seeking to establish infringement of that claim limitation.

Because there is no genuine issue of fact as to whether PROMUS uses a "biocompatible" polymer, when that term is properly construed, BSC is entitled to summary judgment of non-infringement.

II. "Coating" and "Applied Thereto" Claim Limitations

As BSC explained in its opening brief, certain claims of the '3286 and '473 patent require a stent with a drug-containing "coating" which is "applied thereto." (*See* BSC's Opening Br. at 20-22.) Just as with the "biocompatible" claim limitation, Cordis ignores BSC's proper construction of both "coating" and "applied thereto," continues to argue its own erroneous claim constructions, and points to numerous immaterial facts that appear relevant only in light of those erroneous constructions.

Under BSC's proposed constructions, the "coating" and "applied thereto" limitations require that the drug-containing polymeric "coating" be attached directly to the metallic stent surface itself. (See Plaintiffs' Opening Markman Brief at 26-27; Plaintiffs' Responsive Markman Brief at 20.) Cordis, however, does not dispute that the PROMUS stent's drug-containing PVDF-HFP coating does not rest on the metallic stent surface. Indeed, as it must, Cordis tacitly admits that a PBMA primer is interposed between the metallic stent and the

Thus, if the Court adopts BSC's proposed construction, there are no genuine issues of material fact that prevent entry of summary judgment.

Rather than addressing BSC's proposed construction, Cordis seeks to distract the Court's attention with irrelevant arguments regarding the meaning of the term "stent." According to Cordis, the claim term "stent" can include not only the metallic stent, but also a primer. (See Cordis Resp. Br. at 11-12.) In support of this argument, Cordis alleges that those of skill in the art often refer to a complete device (i.e. a metallic stent and all its coatings) as a "stent." (See id.) This is of no relevance here, as it does not change the fact that intrinsic record dictates that "coating" and "affixed thereto" be construed in the manner proposed by BSC and that these constructions necessitate a finding of no infringement. Further, if "stent" were defined in the manner Cordis suggests, the PROMUS stent would have no "coating" at all. Cordis points to no evidence that one of skill in the art would understand "stent" to mean a metallic stent plus only its primer. Instead, Cordis only highlights that those of skill sometimes refer to device and all its coatings as a "stent." Under such a construction, since all of the PROMUS stent's polymeric coatings would be part of the "stent" itself, no structure is left to meet the claims' "coating" limitations.

Cordis also argues that the PROMUS stent can satisfy the "coating" limitation because its PBMA primer purportedly includes some drug. (*See* Cordis Resp. Br. at 13.) In support of this argument, Cordis cites to the Declaration of Dr. Mikos, which accompanied its opposition brief. (*See id.* at 14.)

As a result, they

should be struck from the case. (*Id.*) If struck, Dr. Mikos's opinions are inadmissible and cannot be used to rebut BSC's summary judgment motion.⁷

In particular, during reexamination,

Dr. Mikos attempted to distinguish a reference – the Ding '313 patent⁸ – that discloses the use of a fluorinated polymer as a topcoat from the subject matter claimed by the patents-in-suit. Among other things, and despite the fact that the Ding '313 patent's fluorinated polymer topcoat is in direct contact with the drug-containing coating, Dr. Mikos argued that the '313 Ding reference "does not suggest use of fluorosilicone or any fluorinated polymer for the drug-containing underlayers...." (*See* Ex. B to BSC's Opening Markman Br., 4/22/09 Mikos Decl. at ¶ 171 (at BSC-A-57)).

It is black letter law that claims cannot be construed one way to achieve allowance and another to establish infringement. *See Southwall Techs. Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576

Cordis's reliance on Dr. Mikos's untimely opinions in its summary judgment opposition highlights the prejudice caused to BSC. Because Dr. Mikos did not fully disclose his opinions within the time frame set by the Court's scheduling order, BSC's own experts did not have an opportunity to rebut those opinions with their own expert reports before opening claim construction and summary judgment briefs were due.

U.S. Patent No. 5,837,313 to Ding (referred to above as the "Ding '313 patent" and attached as Ex. 55) is one of several prior art patents that teach the use of polymer coated stents to achieve controlled delivery of therapeutic agents to a vessel wall to treat restenosis. The Ding '313 patent was cited during the reexaminations of the '7286, '3286, and '473 patents as a reference that renders the claims of those patents invalid as obvious. (See, e.g., Ex. 5 at BSC-SJA-0093-0101.) It has also been cited by BSC's experts. The Ding '313 patent, among other things, teaches the use of stents coated with multiple polymer coatings, including a topcoat and drug-containing undercoat, and notes that various types of polymers can be used in connection with these coatings. (See, e.g., Ex. 55, Ding '313, 3:27-45 (BSC-SJA-1152).) As noted during reexamination, the Ding '313 patent, via its reference to a related application, discloses the use of fluorinated polymers in a stent's topcoat. (See Ex. 5 at BSC-SJA-0094.)

(Fed. Cir. 1995); *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991). The Court should disregard these inconsistent opinions.

As explained in BSC's opening brief, the claims of the '3286 patent require that the "coating" which is "applied" to the metallic stent surface "comprise[] a biocompatible polymer/drug mixture." (See BSC's Opening Br. at 20-21.) Under BSC's proposed construction, a "mixture" is a "composition in which substances are combined and intermingled." (Id. at 20.) Similarly, the claims of the '473 patent require that the "coating" "comprise a mixture of a biocompatible polymeric carrier and a therapeutic agent." (Id.) BSC has also proposed that "carrier" be defined to mean "a therapeutic agent-containing material co-formulated with the therapeutic agent." (Id.) Cordis has not alleged that everolimus is combined with PBMA prior to its application to the stent or dispersed throughout the PROMUS stent's PBMA primer as would be required for these components to constitute a "polymeric carrier" or a "mixture" of drug and polymer. Thus, under BSC's proposed constructions, the PROMUS stent lacks a "coating" that is "applied thereto" even if some minimal amount of everolimus is present in the PBMA primer. This is simply not a material fact that prevents entry of summary judgment and Cordis's arguments to the contrary are nothing more than re-hashed claim construction positions.

Finally, just as with the "biocompatible" limitation discussed above, the doctrine of equivalents cannot be used to extend the "coating" and "applied thereto" limitations to the PROMUS stent. While Cordis argues that "using a primer is not the *antithesis* of applying a coating to a stent" (Cordis Resp. Br. at 13), this is not the proper inquiry. Allowing a stent, such as PROMUS, whose drug-containing coating is *not* directly affixed to the stent surface to meet a

limitation that requires that coating to be directly affixed to the stent surface would impermissibly read this limitation out of the claims. *See Warner-Jenkinson*, 520 U.S. at 29-30; *Carnegie Mellon Univ.*, 541 F.3d at 1129; *Asyst Techs.*, 402 F.3d at 1195; *Freedman Seating*, 420 F.3d at 1358; *Moore U.S.A.*, 229 F.3d at 1106.

Because there is no genuine issue of fact as to whether the PROMUS includes a "coating" that is "applied thereto," when those terms are properly construed, BSC is entitled to summary judgment of non-infringement.

III. "Polymer" and Other Similar Claim Limitations

All of the asserted claims of the '7286, '3286, and '473 patents require the use of specific types of "polymer(s)" as drug carriers. (See BSC's Opening Br. at 22-28.) As BSC explained in its opening brief, PROMUS does not meet these limitations because it employs a copolymer as a drug carrier. (See id.)

Apparently recognizing the weakness of its literal infringement arguments, Cordis begins its discussion of the "polymer" claim limitations by arguing that the PROMUS stent infringes under the doctrine of equivalents. According to Cordis, application of a claim limit requiring the presence of a drug-containing "polymer" to a device that includes only a drug-containing copolymer would not read the "polymer" limitation out of the claims. Central to Cordis's position is the assertion that the "specification here does not distinguish polymers and copolymers." (Cordis Resp. Br. at 14.) Nothing could be further from the truth. Cordis fails to acknowledge that the *claims* of the patents-in-suit (which are, of course, part of the specification) themselves explicitly distinguish polymers from copolymers. (*See* Plaintiffs' Opening Markman Brief at 14-17; Plaintiffs' Responsive Markman Brief at 15-18.) Because these claims make clear that, for purposes of the patents-in-suit, a polymer is *not* a copolymer, the doctrine of equivalents cannot be used to re-embrace this subject matter. *See Warner-Jenkinson*, 520 U.S. at

29-30; Carnegie Mellon Univ., 541 F.3d at 1129; Asyst Techs., 402 F.3d at 1195; Freedman Seating, 420 F.3d at 1358; Moore U.S.A., 229 F.3d at 1106. Thus, Cordis's arguments in this regard do not weigh against the entry of summary judgment of non-infringement.⁹

Only after ineffectually arguing that PROMUS meets the "polymer" limitations under the doctrine of equivalents does Cordis move on to literal infringement. According to Cordis, the PROMUS stent's PBMA primer can literally satisfy the various "polymer" limitations. While PBMA, unlike PVDF-HFP, is not a copolymer, this argument fails for the same reason described in connection with the "coating" and "applied thereto" limitations discussed above.

As a result, these opinions should be struck from the case, are not admissible evidence, and cannot be used to defeat a motion for summary judgment.

Second, even if Cordis is permitted to rely on Dr. Mikos's opinion, and assuming that this opinion is correct (which it is not), the PROMUS stent still does not meet the various "polymer" limitations. As noted above and in BSC's opening brief, the asserted claims of the '7286, '3286, and '473 patents respectively require that this "polymer" be part of a "polymeric carrier," "polymer/drug mixture," or "mixture of ... polymeric carrier and ... therapeutic agent." (See BSC's Opening Br. at 22-29.) Under BSC's proposed constructions, this means that the "polymer" must be co-formulated with drug prior to application to the stent and have drug

Cordis also attempts to establish that the PVDF-HFP copolymer utilized by the PROMUS stent is insubstantially different from the "polymer" required by the claims. (See Cordis Resp. Br. at 14.)

dispersed throughout it. (See id.) While Cordis alleges that "some" everolimus makes its way into the PROMUS stent's PBMA primer, it does not and cannot claim that the everolimus is coformulated with PBMA prior to its application to the stent. Similarly, Cordis does not and cannot claim or that everolimus is dispersed throughout the PBMA as would be required for this primer to be a "polymeric carrier" or "mixture" of drug and polymer. Thus, under BSC's proper constructions, the PROMUS stent lacks a "polymer" even if some minimal amount of everolimus is present in the PBMA primer.

Cordis's arguments in this regard are nothing more than claim construction proposals recast as "factual issues," and simply do not create any genuine issues of material fact that prevent the entry of summary judgment.

IV. "Present in an Amount Effective to Inhibit Neointimal Proliferation" Claim Limitation

Just as it did with the other limitations addressed by BSC's non-infringement summary judgment motion, Cordis again ignores and fails to apply BSC's proper construction of "present in an amount effective to inhibit neointimal proliferation" when it argues that the amount of drug used by PROMUS satisfies this particular claim limitation.

For reasons set forth in BSC's claim construction briefing, the term "present in an amount effective to inhibit neointimal proliferation" should be construed to mean "an amount sufficient to stop neointimal proliferation." (See Plaintiffs' Opening Markman Brief at 27-29; Plaintiffs' Responsive Markman Brief at 20-23.) There can be no dispute that PROMUS does not stop neointimal proliferation. Cordis itself notes that PROMUS only "stops most of the smooth muscle cells in the artery from proliferating." (Cordis Resp. Br. at 2 (emphasis added).) Similarly, Cordis admits that PROMUS results in "very low rates of restenosis." (Id.)

In making these statements,

Cordis implicitly concedes that at least *some* neointimal proliferation occurs after PROMUS is implanted. Importantly, however, Cordis never once argues that PROMUS entirely stops neointimal proliferation as would be required for it to satisfy this claim limit under BSC's construction. As a result, there are no genuine issues of material fact that would preclude the entry of summary judgment.

Rather than concede that PROMUS does not infringe under BSC's construction, Cordis continues to apply its own erroneous claim construction proposal (which only requires the stent to include "[a]n amount [of drug] that works to reduce neointimal proliferation"). In particular, Cordis notes that PROMUS "stops a sufficient amount of the smooth muscle cells in the neointima from proliferating to achieve a clinically effective treatment of restenosis." (Cordis Resp. Br. at 16.) While the clinical efficacy and level of proliferation inhibition achieved by PROMUS might have some bearing if Cordis's construction is adopted, this certainly does not establish that PROMUS stops neointimal proliferation or create genuine issues of fact that would prevent entry of summary judgment. The PROMUS stent simply cannot literally infringe claims 1-5 of the '7286 patent, claims 32-39, 51, 52, 63, 67, 69-77 of the '3286 patent, or claims 1-5 of the '473 patent if the Court adopts BSC's construction of "present in an amount effective to inhibit neointimal proliferation."

As noted in BSC's opening brief, and despite Cordis's arguments to the contrary, PROMUS also cannot infringe these claims under the doctrine of equivalents. (See BSC's

Opening Br. at 30.) Again, allowing a stent which permits *some* neointimal proliferation to satisfy a claim limitation that *does not allow for any* neointimal proliferation would read the "present in an amount effective to inhibit neointimal proliferation" limitation out of the claims. The doctrine of equivalents cannot be used to this end. *See Warner-Jenkinson*, 520 U.S. at 29-30; *Carnegie Mellon Univ.*, 541 F.3d at 1129; *Asyst Techs.*, 402 F.3d at 1195; *Freedman Seating*, 420 F.3d at 1358; *Moore U.S.A.*, 229 F.3d at 1106.

Because there is no genuine issue of fact as to whether PROMUS "inhibits neointimal proliferation," when that term is properly construed, BSC is entitled to summary judgment of non-infringement.

CONCLUSION

For the foregoing reasons, and for the reasons articulated in its opening brief, BSC respectfully requests that the Court grant this motion for summary judgment of non-infringement.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Andrew A. Lundgren

Josy W. Ingersoll (#1088) [jingersoll@ycst.com] Karen L. Pascale (#2903) [kpascale@ycst.com] Karen E. Keller (#4489) [kkeller@ycst.com] Andrew A. Lundgren (#4429) [alundgren@ycst.com] The Brandywine Building, 17th Floor 1000 West Street Wilmington, DE 19801 (302) 571-6600

Attorneys for Plaintiffs
Boston Scientific Corporation and
Boston Scientific Scimed, Inc.

Of Counsel:

Richard L. DeLucia
Paul M. Richter
Michael K. Levy
KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200

Dated: October 16, 2009

CERTIFICATE OF SERVICE

I, Andrew A. Lundgren, Esquire, hereby certify that on October 27, 2009, I caused to be electronically filed a copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Steven J. Balick, Esquire [sbalick@ashby-geddes.com]
John G. Day, Esquire [jday@ashby-geddes.com]
Lauren E. Maguire, Esquire [lmaguire@ashby-geddes.com]
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
Wilmington, DE 19801

I further certify that on October 27, 2009, I caused a copy of the foregoing document to be served by e-mail on the above-listed counsel and on the following non-registered participants in the manner indicated:

By E-Mail

David T. Pritikin, Esquire [dpritikin@sidley.com]
William H. Baumgartner, Esquire [wbaumgartner@sidley.com]
Russell E. Cass, Esquire [rcass@sidley.com]
Jon M. Spanbauer, Esquire [jspanbauer@sidley.com]
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Andrew A. Lundgren

Josy W. Ingersoll (No. 1088) [jingersoll@ycst.com] Karen L. Pascale (No. 2903) [kpascale@ycst.com] Karen E. Keller (No. 4489) [kkeller@ycst.com] Andrew A. Lundgren (No. 4429) [alundgren@ycst.com] The Brandywine Building 1000 West Street, 17th Floor Wilmington, Delaware 19801 (302) 571-6600 Attorneys for Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc.

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